DEPARTMENT OF HEALTH AND HUMAN SERVICES

9455'd

Food and Drug Administration
Los Angeles District
Pacific Region
19701 Fairchild
Irvine, CA 92612-2445

Telephone: 949-608-2900
FAX: 949-608-4415

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

January 5, 2004

Mr. Richard Ang, President
Mandalay Trading Corporation
903 South Azusa Ave.
City of Industry, CA 91748

W/L 17-04

Dear Mr. Ang:

On December 4, 2003, the Food & Drug Administration (FDA) conducted an inspection of your facility located at 903 South Azusa Ave., City of Industry, CA 91748. The inspection was conducted to determine your firm's compliance with FDA's seafood processing regulations, Title 21 of the Code of Federal Regulations Part 123 (21 CFR § 123).

The seafood processing regulations, which became effective on December 18, 1997, require that you have and implement written verification procedures to verify that you foreign suppliers have implemented a preventive system of food safety controls known as Hazard Analysis Critical Control Point (HACCP) in accordance with U.S. requirements. In accordance with the seafood processing regulations, 21 CFR § 123.6(g), failure of a processor to have and implement a HACCP plan that complies with the requirements of that section, or otherwise operate in accordance with the requirements of Part 123, renders the fishery products adulterated within the meaning of Section 402(a)((4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly, your salted anchovies and canned mackerel in oil are adulterated in that the products have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby the may have been rendered injurious to health. You may find the Act and the seafood HACCP Regulations through links in FDA's home page at www.fda.gov.

During our inspection, the FDA investigator observed serious deviations in your seafood HACCP program, including failure to comply with the importer verification requirements listed in the Seafood HACCP Regulation, Section 123.12, Special Requirements for Imported Products. The FDA investigator also provided you with a copy of the FDA 483, Inspectional Observations, which presents his evaluation of your firm's performance regarding various aspects of the HACCP requirements.

The HACCP violations of utmost concern to us are as follows:

1. You must implement an affirmative step which ensures that the fish and fishery products you import are processed in accordance with the Seafood HACCP Regulation, to comply with 21 CFR 123.12(a)(2)(ii). However, your firm did not perform an affirmative step for:

   Salted anchovies manufactured by [redacted] and canned mackerel in oil manufactured by [redacted] both from the [redacted]

2. You must have product specifications that are designed to ensure that the fish and fishery products you import are not injurious to health, to comply with 21 CFR 123.12(a)(2)(i). However, your firm does not have product specifications for:

   Salted anchovies and canned mackerel in oil imported from the [redacted]

This inspection was also a follow-up to a previous inspection conducted June 26 & July 1, 2003 to verify that corrective actions had taken place for salted anchovies. A copy of the FDA 483 was also given to you as a result of that inspection. At the most recent inspection, you informed the investigator that you had not made any of the corrective actions for the salted anchovies.

The above identified deviations are not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure that all seafood products processed and distributed by your firm are in compliance with the Act and all requirements of the federal regulations.

This inspection was also conducted to follow-up on sold and distributed refused entries imported into the United States by your firm. The refused entries, listed below, were distributed into U.S. commerce without a proper FDA release and despite FDA detention. Title 21 Code of Federal Regulations (CFR) section 1.90, requires the importer to hold an entry intact pending receipt of a May Proceed or Release Notice from FDA. On July 8, 2003, September 30, 2003 and October 14, 2003 the following discrepancies were found:

Entry Number	Product	Invoiced Amount	Missing Amount
[redacted]	Salted Anchovies	[redacted]	[redacted] Cartons
	Salted Tamarind Candy		[redacted] Cartons
	Sweet Tamarind Candy		[redacted] Cartons
	Montano Bangus in Oil		[redacted] Cartons

Entry [redacted]
Salted Anchovies were Detained Without Examination on July 14, 2003 based on guidance in Import Alert 16-13 (" Detention Without Physical Examination of Anchovy or Bagoong Products from Philippines"), because the articles appeared to be adulterated within the meaning of Section 402(a)(3) of the Act, 21 U.S.C. § 342(a)(3), in that they may consist in whole or in part of a filthy, putrid, or decomposed substance, or are otherwise unfit for food in that they contains E. Coli/Coliforms. A redelivery request for this product was submitted to Customs and

Border Protection (CBP). On October 14, 2003 our investigators examined the product that your firm redelivered under entry number [redacted], however it was revealed that the product presented was not the salted anchovies initially imported and detained. This information was provided to CBP.

Entries [redacted] &
Sweet and salty tamarind candy products were Detained Without Examination on June 2, 2003 based on guidance in Import Alert 21-07 ("Detention Without Physical Examination of All Tamarind Products (Fresh and/or Processed) From All Shippers From All Countries"), because the articles appeared to be adulterated within the meaning of Section 402(a)(3) of the Act, 21 U.S.C. § 342(a)(3), in that they may consist in whole or in part of a filthy, putrid, or decomposed substance or are otherwise unfit for food. These products were refused admission because proof of compliance was not submitted. On October 14, 2003 our investigators examined the products that were previously refused entry that your firm offered for exportation after redelivery to a Customs bonded warehouse. Upon examination, it was revealed that this entry was still missing [redacted] cartons of salted tamarind candy and [redacted] cartons of sweet tamarind candy. This information was forwarded to CBP.

Entry [redacted]
Montano Bangus(milkfish) in oil was Detained Without Examination on January 3, 2003 for failure to file information regarding its process as required for acidified or low-acid foods, pursuant to Title 21 of the Code of Federal Regulations (CFR) sections 108.25(c)(2) and 108.35(c)(2). Of the [redacted] cartons invoiced, [redacted] cartons could not be located during the examination on July 8, 2003. A request to redeliver was submitted to CBP on July 15, 2003.

You should take prompt measures to correct these Seafood HACCP and importation deviations. Failure to promptly correct the Seafood HACCP deviations may result in regulatory action without further notice. Such action may include seizure and/or injunction. FDA may also detain your seafood products without examination. Under such conditions, FDA will not issue any Certificates for Export or European Union Health Certificates for any of the affected fish and fishery products processed at your facility.

In addition, future premature distribution of imported product may result in FDA requiring that future shipments be held in secured storage. Secured storage would be under the supervision and direction of CBP, such as in a bonded warehouse. Your firm would be responsible for all costs incurred in secured storage.

As the importer of record, it is your responsibility to ensure that imported product meets all requirements of the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder and hold the product intact until it is released by FDA. Your firm has an ongoing responsibility to ensure that all import brokers, consignees and others working on your behalf hold the imported product intact unless and until it is released or destroyed. We remind you that introduction into or receipt in interstate commerce of any article that is adulterated or misbranded is a violation of the Federal Food, Drug and Cosmetic Act, and may result in domestic seizure or other sanctions, including injunction or prosecution.

Please notify this office in writing, within fifteen (15) working days of receipt of this letter of specific steps you have taken to correct these violations, including an explanation of each step taken to prevent their recurrence. Your response should include copies of any available documentation demonstrating that corrections have been made. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time frame within which the corrections will be completed.

Your written reply should be directed to:

U.S. Food & Drug Administration
Attn: Director, Import Operations Branch
Los Angeles District
222 West 6th Street, Suite 700
San Pedro, CA 90731

If you have questions regarding the implementation of the Seafood HACCP Regulation, you may contact Ruth P. Dixon, Compliance Officer, at (310) 971-2299.

Sincerely,

Alonza Cruse
District Director